

Senator John Breaux

Opening Statement

*Buyer Beware: Public Health Concerns of Counterfeit Medicines*

Special Committee on Aging

July 9, 2002

Good afternoon and thank you all for coming. I especially want to welcome Mr. Rick Roberts who traveled all the way from Colorado to share his story with us today. I also welcome the Committee's ranking member, Senator Larry Craig, and my other colleagues as we explore this important public health issue.

Last September, I held a hearing to examine the marketing practices of some dietary supplement companies. What I found was that unscrupulous con men were making unsubstantiated health care claims about products which undergo practically no Food and Drug Administration (FDA) approval process. As unsavory as these characters were, none of their products claimed to have FDA approval, they were simply gaming the system. Today's hearing, "Buyer Beware: Public Health Concerns of Counterfeit Medicine," is being called to examine an even worse practice - the counterfeiting of FDA-approved prescription pharmaceuticals.

The term "counterfeit" will be used today to discuss pharmaceutical products which fall under three broad headings. The first consists of products which contain the correct active ingredients but have either incorrect dosages, have expired or have been re-labeled. These drugs could trigger allergic reactions or simply be ineffectual. The next group consists of products with no active ingredients. These products may sound safe, but in fact they prevent patients from receiving proper medical treatment and could effectively lead to a patient's untimely death. Finally, the third group consists of products containing the wrong ingredients. These drugs may actually contain other medicines or toxic substances which can lead to immediate health care problems.

It was reported last year that nearly *eight percent of drugs imported into the U.S. are fake*. The World Health Organization has estimated that about eight percent of the medicines available worldwide are counterfeit. These statistics are troubling. The U.S. maintains the most rigorous pharmaceutical regulatory system in the world, but high prescription drug costs and the growing Internet marketplace make the U.S. an increasingly attractive target for this unscrupulous industry. Additionally, we will hear today that counterfeits are entering our country not only through personal importation and the Internet, but also on the shelves of trusted retail pharmacies.

The Congress has held dozens of hearings on the rising costs of prescription drugs and

we have heard countless stories of individuals and families devastated by the financial burdens of treating chronic illnesses. Today's hearing will illustrate that we cannot look abroad for the solution to the prescription drug dilemma. We in Congress must do all that we can to provide a meaningful, affordable prescription drug plan for our nation's seniors and we must do it before more of our vulnerable citizens jeopardize their lives for a solution.

I look forward to learning more about this issue from our distinguished panelists and I welcome recommendations about what can be done to stop this public health crisis in its tracks.